IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

JESSICA WELLS, individually and as next friend of J. W.,	)	
Plaintiffs,	)	
vs.	)	Case Number CIV-12-973-C
ALLERGAN, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Jessica Wells, individually and as next friend of J.W.,[1] a minor, filed the present suit on September 1, 2011, in Oklahoma County District Court, alleging that the Botox injections that J.W., a minor, received to treat his lower limb spasticity resulted in botulinum poisoning, causing him to suffer numerous injuries. (Notice of Removal, Dkt. No. 1, Ex 1., Ex. 2 at 5-6.) On September, 4, 2012, Defendant Allergan, Inc., the manufacturer of Botox, removed this suit to federal court. Defendant now moves for partial summary judgment (Dkt. No. 91), asserting that Plaintiffs' strict liability and negligence causes of action fail as a matter of law. For reasons more fully set forth herein, the Court now DENIES Defendant's Motion.

I. BACKGROUND

[1] Pursuant to Fed. R. Civ. P. 5.2(a), "[u]nless the court orders otherwise, in an electronic or paper filing with the court that contains . . . the name of an individual known to be a minor . . . a party or nonparty making the filing may include only: . . . (3) the minor's initials." Although the parties referred to J.W. by full name in their briefs, the Court cautions them to abide by Rule 5.2 in the future and only use J.W.'s initials.

Defendant Allergan manufactures Botox, a purified form of botulinum toxin type A that the FDA has approved for a variety of uses. In addition to the FDA-approved "on-label" uses, health care providers also commonly use Botox to treat other conditions, something known as an "off-label" use. Although many health care providers treat pediatric spasticity with Botox injections, Botox has not been approved by the FDA for such a use, making it "off label."

In late 2007, the FDA contacted Allergan because of concerns about reports of pediatric botulism following the use of Botox. In response, Allergan submitted an evaluation of data on pediatric cases to the FDA and also proposed a revised Botox package insert with the following language: "In pediatric clinical trials, doses greater than 8 U/kg[2] have not been adequately studied." (Def.'s Br., Dkt. No. 91, at 6.) After a consumer watchdog group petitioned the FDA to require increased warnings about the risk of the botulinum toxin spreading outside the injected muscle, on February 8, 2008, the FDA publically announced an investigation into the safety of Botox and the link between Botox and botulism ("FDA Early Communication"). Allergan again proposed to add a warning to its packaging[3] but on March 4, 2008, the FDA rejected Allergan's proposed labeling revisions. The FDA explained that "[a]s written, [the warning] implies that doses less than or equal to 8 U/kg

[2] U/kg stands for unit of Botox per kilogram of the patient's body weight.

[3] Allergan's second proposed change included language similar to that of its first proposed revision: "In pediatric clinical trials for pediatric cerebral palsy, doses greater than 8 U/kg have not been adequately studied. Post-marketing reports of possible distant spread of toxin have been very rarely reported in pediatric patients with co-morbidities, predominantly with cerebral palsy, who received > 8 U/kg." (Id. at 7.)

have been adequately studied in clinical trials for cerebral palsy; however, this is not an approved use in the United States." (Id. at 8 (emphasis added).) In response, Allergan proposed a modified revision: "Post-marketing reports of possible distant spread of toxin have been very rarely reported in pediatric patients with co-morbidities, predominantly with cerebral palsy, who received > 8 U/kg." (Id.) The FDA did not comment on this proposal. (Pls.' Resp., Dkt. No. 112, at 17.)

A little over a year later, the FDA informed Allergan that it would have to change its Botox label to include a new black box warning and distribute a "medication guide" to doctors that doctors would then be required to pass on to their patients. Neither the FDA's new label warning nor the medication guide included Allergan's previously suggested 8 U/kg language. Instead, the FDA's black box warning stated:

> Postmarketing reports indicate that the effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties . . . Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity . . . In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

(Def.'s Br. at 9.) Similarly, the medication guide warned:

> Spread of toxin effects: In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body; double vision; blurred vision and drooping eyelids; hoarseness or change or loss of voice

> (dysphonia); trouble saying words clearly (dysarthria); loss of bladder control; trouble breathing; trouble swallowing.

(Id. at 9-10.)

Although Allergan requested several changes to the new packaging, including removing the word "botulism" from the black box warning, Allergan did not re-assert the need to include an 8 U/kg maximum safe dose warning. Allergan began distributing the revised package insert and required medication guide in August of 2009. Both warnings were in effect at the time J.W. received his Botox injections.

J.W. is a six-year-old boy[4] who was born with a neurologic condition called Leukodystrophy. As a result of his condition, J.W. suffers lower-limb spasticity. At the time relevant to this action, J.W.'s treating physician was Dr. Edward Wright, a pediatric physiatrist who practices at The Children's Center in Bethany, Oklahoma. Dr. Wright has used Botox to treat pediatric spasticity for approximately fifteen years. In 2005, Dr. Wright responded to an Allergan customer survey and reported that on average he dosed his pediatric spasticity patients with 20 U/kg. However, in 2007, Dr. Wright treated a pediatric patient who had contracted botulism after receiving Botox injections of 30 U/kg. Afterward, Dr. Wright requested information from Allergan regarding maximum dosing levels for pediatric spasticity and information on cases of botulism following Botox use in children.

[4] J.W. is currently six years old. He was four years old when he received the March 2010 Botox injections.

Allergan responded to Dr. Wright's inquiry in a letter dated October 31, 2007. Allergan's letter did not specifically warn Dr. Wright that Allergan considered 8 U/kg the maximum safe dose. Instead, Allergan stated:

> The use of BOTOX® for the treatment of cerebral palsy is not a U.S. FDA approved indication. In the more than 45 countries around the world where various symptoms associated with cerebral palsy are approved by respective health agencies, the recommended dosing is approximately 4 Units/kg with a maximum of 200 Units total body dose based on data from Allergan's clinical studies.

(Pls.' Resp., Ex. 10 at 1 (emphasis added).) In addition to the information relating to the recommended dosage in other countries, Allergan also referred Dr. Wright to dosing guidelines suggesting a maximum dose of 16 U/kg or 400 units, whichever is less, and studies in which children were given an average dose of 16.6 U/kg, 19.1 U/kg, and 30 U/kg.

Because Dr. Wright had also requested information relating to post-marketing reports of botulism, Allergan disclosed two cases where pediatric patients had experienced botulism-like symptoms following Botox injections: one incident where a child in one of the studies cited experienced "mild, generalized botulism" after receiving 23 U/kg of Botox, and one case of botulism-like syndrome that had been reported to the South Texas Poison Control Center. (Id., Ex. 10 at 2.) Although Allergan only informed Dr. Wright of these two cases of pediatric botulism following Botox injections, its subsequent report to the FDA, dated December 19, 2007, indicates it was aware of many more cases. (Id., Ex. 12.)

Dr. Wright continued to treat his pediatric patients with Botox after receiving Allergan's letter. Following the FDA's label change in 2009, Dr. Wright changed his

informed consent form to include the new black box warning about the risk of distant spread of the botulinum toxin. On March 29, 2010, Dr. Wright injected J.W. with 200 units of Botox, or 18.33 U/kg,[5] to treat J.W.'s lower-limb spasticity. Plaintiffs allege that the Botox injections resulted in botulinum poisoning, causing J.W.'s legs and body to swell and eventually requiring hospitalization, mechanical ventilation, and tube feeding. Although J.W. has now been extubated, Plaintiffs allege that he suffers from permanent diminishment of his breathing capacity and permanent weakness, loss of strength, and muscle atrophy. J.W. also has developed a seizure disorder and has had a total of five episodes of seizures. Plaintiffs allege Defendant Allergan should be held liable under both strict liability and negligence theories for failure to warn about the risks of distant spread of toxin, botulism or botulism-like symptoms, and dose-related effects, meaning side effects are more likely to occur at higher doses.

II. LEGAL STANDARD

Summary judgment is proper if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it affects the disposition of the substantive claim. Anderson v. Liberty Lobby, Inc., 477 U.S. 247 (1986). The party seeking summary judgment bears the initial burden of demonstrating the basis for its motion, and identifying those portions of "'the pleadings, depositions, answers to interrogatories, and admissions on

[5] J.W. weighed 10.8 kilograms at the time of injection.

file, together with the affidavits, if any,'" that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (citation omitted). If the movant satisfactorily demonstrates an absence of genuine issue of material fact with respect to a dispositive issue for which the non-moving party will bear the burden of proof at trial, the non-movant must then "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" Id. at 324. A court considering a summary judgment motion must view the evidence and draw all reasonable inferences therefrom in the light most favorable to the nonmoving party. Kendrick v. Penske Transp. Servs., Inc., 220 F.3d 1220, 1225 (10th Cir. 2000).

III. ANALYSIS

A. Count I: Strict Liability Failure to Warn

Oklahoma has adopted the principles set forth in § 402A of the Restatement (Second) of Torts and holds manufacturers strictly liable for the products they introduce into the stream of commerce. McKee v. Moore, 1982 OK 71, ¶ 4, 648 P.2d 21, 23. If a manufacturer places a product into "the hands of the ultimate consumer without adequate warnings of the dangers involved in its use," the product "may be considered unreasonably unsafe or defective," "even if [it] is faultlessly designed and the manufacturer has exercised all possible care in the preparation and sale of [the] product." Id. Drug manufacturers, like manufacturers generally, have "a duty to warn the consumer of potential dangers which may occur from the use of the product when it is known or should be known that hazards exist."

Id. Adequate warnings are particularly important for products like prescription drugs, which "are incapable of being made safe, but are of benefit to the public despite the risk." Edwards v. Basel Pharm., 1997 OK 22, ¶ 7, 933 P.2d 298, 300.

In this case, Plaintiffs allege Defendant Allergan should be held strictly liable for failure to warn about the risks of distant spread of toxin, botulism or botulism-like symptoms, and dose-related effects, meaning side effects are more likely to occur at higher doses. Defendant Allergan raises three defenses to Plaintiffs' strict liability claim. First, Defendant argues that the "learned intermediary doctrine" bars liability because when it warned Dr. Wright of the risks associated with Botox injections, it also satisfied its duty to warn Plaintiffs. Second, Defendant asserts that under Wyeth v. Levine, 555 U.S. 555 (2009), federal law preempts any state duty to warn Plaintiffs or Dr. Wright about the 8 U/kg maximum safe dose. Finally, Defendant argues that summary judgment is appropriate because Plaintiffs cannot establish causation, a necessary element of their claim.

1. Learned Intermediary Doctrine

The "learned intermediary doctrine" "operates as an exception to the manufacturer's duty to warn the ultimate consumer, and shields manufacturers of prescription drugs from liability if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶ 8, 933 P.2d at 300. The rationale for this exception is "that the doctor acts as a learned intermediary between the patient and the prescription drug manufacturer by assessing the medical risks in light of the patient's needs." Id. However, "[a]ny warning given to physicians . . . is not sufficient." Ross v. Jacobs, 1984 OK CIV APP

17, ¶ 10, 684 P.2d 1211, 1213 (emphasis added). The warning to the physician "must be adequate" to satisfy the drug manufacturer's duty to warn. Id. (emphasis added).

For summary judgment to be proper, "'reasonable [jurors] in the exercise of fair and impartial judgment'" must not be able to differ on the question of whether Defendant Allergan's warning to Dr. Wright was adequate. Id. at 1213-14 (quoting Stuckey v. Young Exploration Co., 1978 OK 128, ¶ 7, 586 P.2d 726, 730). Whether a warning was adequate is generally a question for the trier of fact, as "most courts have been reluctant to decide adequacy of warning as a matter of law." Id. at 1214. However, the Court can decide that a warning was adequate as a matter of law if it was "'accurate, clear and unambiguous'" and "reasonable under the circumstances." Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 853 (10th Cir. 2003) (quoting Felix v. Hoffmann-LaRoche, Inc., 540 So.2d 102, 105 (Fla. 1989)). Both the Tenth Circuit and the Oklahoma Court of Appeals have acknowledged the following five considerations as "relevant in determining whether a warning is adequate as a matter of law":

> "1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, . . . 5. the means to convey the warning must be adequate."

Id. (quoting Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994)); see also Ross, 1984 OK CIV APP 17, ¶ 17, 684 P.2d at 1214.

Defendant Allergan contends that it "presented unequivocal evidence that it fulfilled its duty to warn Dr. Wright about the risks of distant spread of toxin and botulism-like symptoms via the most direct medium—the 2009 FDA-approved labeling." (Def.'s Reply, Dkt. No. 122, at 1.) At the time of J.W.'s injections, Botox's package insert included the FDA-required black box warning, which specifically cautioned that "[p]ostmarketing reports indicate that the effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. . . . The risk of symptoms is probably greatest in children treated for spasticity." (Def.'s Br. at 16.) Notwithstanding Defendant's compliance with the FDA's labeling regulations, Plaintiffs argue that Defendant Allergan "understated the risk of spread of toxin and botulism to Dr. Wright" on numerous occasions. (Pls.' Resp. at 12.)

Plaintiffs' argument relies on the fact that Dr. Wright directly sought information on maximum safe dosing for pediatric patients and post-marketing reports of botulism from Allergan in October of 2007, years before J.W.'s injections. According to Plaintiffs, had Allergan been forthcoming in its response to Dr. Wright's letter, "this entire unfortunate injury could have been avoided." (Id. at 13.) Dr. Wright asked Allergan whether there was a maximum safe dosage for pediatric spasticity patients. However, despite having an internal maximum safe dose of 8 U/kg, Allergan responded to Dr. Wright by directing him to studies using up to 30 U/kg. Allergan also failed to disclose more than two cases of pediatric botulism following Botox injections, even though it had many more cases in its database. Dr. Wright has testified that he would have liked to have known information relating to

pediatric deaths and Allergan's internal 8 U/kg maximum dose and that because of what he has learned in this case, he has now reduced the doses of Botox he injects in his patients.

In denying summary judgment, the Court "need not conclude that the warning given by [Allergen] was inadequate . . . [just] that the issue is one where reasonable [persons] could differ." Ross, 1984 OK CIV APP 17, ¶ 18, 684 P.2d at 1214. Here, summary judgment is inappropriate because reasonable persons could differ on whether Allergan adequately warned Dr. Wright about the risk of toxin spread and botulism, given Allergan's evasive response to Dr. Wright's direct inquiry in 2007. Because this case involves an off-label use, Allergan should have been particularly forthcoming when asked about information relating to a specific question by an individual doctor. Thus, the learned intermediary doctrine does not afford Defendant summary judgment under the standard set out in Thom and Ross.[6]

2. Conflict Preemption

Defendant Allergan also argues that even if state tort law required it to warn Dr. Wright of the 8 U/kg maximum safe dose for pediatric patients, it cannot be held liable for failing to do so because federal law preempted its obligation. The Supreme Court recently examined whether federal labeling requirements preempt state tort liability in failure to warn

[6] Plaintiffs also argue that there is an applicable exception to the learned intermediary doctrine. The Oklahoma Supreme Court has recognized there is an exception to the learned intermediary doctrine "when the Food and Drug Administration mandates that a warning be given directly to the consumer." Edwards, 1997 OK 22, ¶ 10, 933 P.2d at 301. Plaintiffs contend that the direct warning mandate applies in this case because the FDA required Allergan to distribute a medication guide for the patient's use. However, as Defendant points out, Allergan fully complied with this requirement by distributing the guides to Dr. Wright with instructions for him to pass the guide on to his patients, the end-users of Botox. (Def.'s Reply at 2 n.1.)

cases. See Wyeth v. Levine, 555 U.S. 555 (2009). In Levine, the drug manufacturer argued that "it [was] impossible for it to comply with both the state-law duties and its federal labeling duties." Id. at 568. The Supreme Court rejected this argument, concluding that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Id. at 570-71. The Court recognized that although a manufacturer must generally receive prior approval to change a drug label, the "changes being effected" ("CBE") regulation permits manufacturers to make label changes before receiving FDA approval, if the change is to "'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage . . . that is intended to increase the safe use of the drug product.'" Id. at 568 (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)). Because the CBE regulation allows drug manufacturers to "unilaterally strengthen" the warnings on their product labels, courts may not find impossibility preemption "absent clear evidence that the FDA would not have approved" the label change required under state law. Id. at 571, 573 (emphasis added). The Supreme Court has not defined the "clear evidence" standard required by Levine, leaving lower courts "'to determine what satisfies this "clear evidence" standard in each case.'" Dobbs v. Wyeth Pharm., 797 F.Supp.2d 1264, 1270 (W.D. Okla. 2011) (quoting Schilf v. Eli Lilly & Co., Case No. CIV-07-4015, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010)); see also Mason v. SmithKline Beecham Corp., 596 F.3d 387, 391 (7th Cir. 2010). However, other than the court in Dobbs, courts have almost "universally found the

manufacturer's evidence inadequate to support conflict preemption." Dobbs, 797 F.Supp.2d at 1270.

In Dobbs, a widow sued Wyeth Pharmaceuticals ("Wyeth") alleging that her husband committed suicide as a result of taking Effexor, a prescription antidepressant. Id. at 1266. The plaintiff contended that the suicide warning in Effexor's packaging was inadequate, subjecting Wyeth to liability for both strict liability and negligent failure to warn. Id. Wyeth argued for impossibility preemption, asserting that "it could not comply with both the duty to warn advanced by plaintiff and the FDA regulations without risking adverse action by the FDA." Id. at 1268. Federal regulations require drug warnings to "be based on 'reasonable evidence of a causal association' between use of the drug and the hazard identified in the warning." Id. at 1272 (quoting 21 C.F.R. § 201.57(c)(6)(i)). In holding that Wyeth had presented clear evidence that the FDA would not have approved a change to Effexor's suicide warning, the court noted that the FDA had consistently rejected proposals for an enhanced suicide warning, both by citizens and drug manufacturers, including Wyeth, because of a lack of scientific evidence supporting a causal connection between Effexor and suicidality in adult patients. Id. at 1273-77.

This case is distinguishable from Dobbs. As in Dobbs, Defendant Allergan has presented evidence that the FDA expressly rejected a specific proposal to revise the Botox warning to include information relating to the 8 U/kg maximum. However, in this case, the FDA did not reject Allergan's revision because there was no scientific basis for the enhanced warning; instead, the FDA clearly explained that it rejected Allergan's proposal because of

fears of back-door off-label promotion. The FDA's response stated: "[a]s written, [the warning] implies that doses less than or equal to 8 U/kg have been adequately studied in clinical trials for cerebral palsy; however, this is not an approved use in the United States." (Def.'s Br. at 8 (emphasis added).) Although manufacturers may include safety information related to off-label uses in their packaging, they may not seek to promote an off-label use by impliedly making an effectiveness claim. (Pls.' Resp., Ex. 35 at 6-7, 9-10, ¶¶ 12, 18, 20.) The FDA's rejection of Allergen's proposal is thus not "clear evidence" that the FDA would have rejected any warning relating to the 8 U/kg maximum safe dose. Because the FDA allowed Allergan to include other safety information related to off-label uses, Allergan has not presented clear evidence that the FDA would have rejected a non-promotional maximum safe dose warning. (See id., Ex. 35 at 16, ¶ 34.)

Moreover, even if federal regulations would have prevented Allergan from altering Botox's label, it still would not have been "impossible" for Defendant to comply with both federal and state law, as Allergan could have informed Dr. Wright of the 8 U/kg maximum in response to Dr. Wright's direct inquiry or during one of the 111 visits Allergan's sales representatives made to Dr. Wright's office. Federal drug labeling regulations do not impede "other appropriate, non-promotional communications to physicians or patients about risks associated with off-label use." (Id., Ex. 35 at 9, ¶ 18.) Defendant was aware that it could communicate with physicians privately about the 8 U/kg maximum without fear of violating federal regulations as it did so on September 14, 2005, in an email to another doctor. (Id. at

26 (citing Ex. 43).) Thus, Allergan has not presented the Court with clear evidence of conflict preemption and summary judgment is inappropriate.

3. Causation

Causation is a necessary element of a products liability action. Prince v. B.F. Ascher Co., 2004 OK CIV APP 39, ¶ 12, 90 P.3d 1020, 1026. To prevail, Plaintiffs "must establish both cause-in-fact (that the product in question caused the injury) and proximate cause (that the manufacturer of the product 'breached a duty to warn of possible detrimental reactions')." Eck v. Parke, Davis & Co., 256 F.3d 1013, 1017 (10th Cir. 2001). A manufacturer's failure to warn is the proximate cause of an injury when it is "a substantial contributing factor in bringing about the harm in question." Id. Under Oklahoma law, Plaintiffs receive the benefit of a "heeding presumption" in failure-to-warn cases, meaning that the law presumes Plaintiffs' "physician would have read and heeded an adequate warning had one been given." Stafford v. Wyeth, 411 F.Supp.2d 1318, 1320 (W.D. Okla. 2006).[7] Defendant "may rebut this presumption 'by establishing that although the prescribing physician would have "read and heeded" the warning or additional information, this would not have changed the prescribing physician's course of treatment.'" Id. at 1320-21 (quoting Eck, 256 F.3d at 1019).

[7] See also Shepherd v. Eli Lilly & Co., ___ F. App'x ___, Case No. 11-3056-cv, 2012 WL 4372949, at *2 (2d Cir. 2012) (applying Oklahoma law); Eck, 256 F.3d at 1018; Woulfe v. Eli Lilly & Co., 965 F.Supp. 1478, 1483 (E.D. Okla. 1997).

Defendant Allergan argues that Plaintiffs cannot establish proximate cause because Dr. Wright had "overwhelming and undeniable" knowledge that distant spread of toxin and botulism-like symptoms were possible side effects of Botox, and Dr. Wright would not have changed his practice even had Allergan warned him that 8 U/kg was its maximum recommended dose. (Def.'s Br. at 23, 27.) Allergan contends that an adequate warning would not have changed Dr. Wright's course of treatment because Dr. Wright failed to alter his practice following Allergan's 2007 "warning" that 4 U/kg was the maximum recommended dose in other clinical trials. (Id. at 27.)

By claiming to have "warned" Dr. Wright that 4 U/kg was the maximum safe dose in 2007, Allergan mischaracterizes its response to Dr. Wright's maximum dose inquiry. In Allergan's response, Allergan stated:

> We received your request for information regarding maximum dosing levels associated with the use of BOTOX® for the treatment of cerebral palsy. . . .
>
> The use of BOTOX® for the treatment of cerebral palsy is not a U.S. F.D.A. approved indication. In the more than 45 countries around the world where various symptoms associated with cerebral palsy are approved by respective health agencies, the recommended dosing is approximately 4 Units/Kg with a maximum of 200 Units total body dose based on data from Allergan's clinical studies.

(Pls.' Resp. Ex. 10 at 1.) The actual text of Allergan's 2007 response indicates that although Allergan informed Dr. Wright that its clinical studies recommended dosing of approximately 4 U/kg, the stated maximum in the letter was 200 Units total body dose—the same total dose as Dr. Wright injected into J.W. in 2010. Moreover, although Allergan made one mention of a recommended 4 U/kg dose, Allergan also referred Dr. Wright to the WE MOVE practice

guidelines recommending a total maximum body dose per visit of the lesser of 16 U/kg or 400 Units, a consensus group with published guidelines of 12 U/kg or a maximum of 300 Units, and recent publications "discuss[ing] the treatment of cerebral palsy populations with comparatively higher doses of BOTOX®," including studies using doses of 16.6 U/kg, 19.1 U/kg, and up to 30 U/kg. (Id., Ex. 10 at 1-2.) The evidence that Allergan included a reference to a recommended 4 U/kg dose in its 2007 letter does not rebut the heeding presumption under Oklahoma law by showing that Dr. Wright would not have changed his practice had Allergan given him an adequate warning that clearly informed him that the company considered anything over 8 U/kg an overdose.[8]

B. Count II: Negligent Failure to Warn

Defendant requests summary judgment on Plaintiffs' negligence claim "for the same reasons" as on "Plaintiffs' strict liability/failure-to-warn cause of action." (Def.'s Br. at 30.) However, because the Court rejected Defendant's arguments for summary judgment on Plaintiffs' strict liability count, it also denies summary judgment for Plaintiffs' negligence cause of action. Allergan also asserts that Plaintiffs' negligent marketing or off-label promotion claim fails because it is not legally cognizable as it is an "improper [private]

[8] The facts of Stafford, on which Defendant relies, are illustrative of the type of evidence that rebuts the heeding presumption. In Stafford, the court found that the treating physician would not have changed his practice, even had he been adequately warned, when he testified that even knowing what he did at the time of the lawsuit, he would still prescribe the same drug to a patient with the same characteristics of the plaintiff, or a woman at the same height and weight with the same family history of heart disease. 411 F.Supp.2d at 1321. In contrast, in this case not only did Dr. Wright testify that he would liked to have had information relating to Allergan's 8 U/kg maximum recommended dose, he in fact has changed his practice based on what he has learned during the course of this lawsuit. (Pls.' Resp. at 18 (citing Exs. 5, 26).)

attempt to enforce the FDCA." (Id.) As Allergan correctly observes, there is no private cause of action under the Food Drug and Cosmetic Act ("FDCA"). However, Plaintiffs argue that their claims of negligent promotion are not attempts to enforce the FDCA, but rather are part of their claims of negligent failure-to-warn. Although Plaintiffs cannot bring a claim against Allergan for violating the FDCA, Defendant's promotional activity can be used as evidence in Plaintiffs' failure-to-warn claim, particularly given that Plaintiffs assert that Defendant failed to warn of a maximum safe dose while promoting the use of much higher doses.

IV. CONCLUSION

Because neither the learned intermediary doctrine nor conflict preemption bars Plaintiffs' claims, Defendant Allergan, Inc.'s Motion for Partial Summary Judgment (Dkt. No. 91) is hereby DENIED.

IT IS SO ORDERED this 31st day of January, 2013.

ROBIN J. CAUTHRON
United States District Judge